UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,082	11/02/2001	David Benjamin Aronow	ADA-005.01	5549

25181   7590   04/25/2005

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EXAMINER
ZEMAN, MARY K

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	10/053,082	ARONOW, DAVID BENJAMIN
Office Action Summary	Examiner	Art Unit
	Mary K. Zeman	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _27 December 2004_.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-30_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-30_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _02 November 2001_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Claims 1-30 are pending in this application.

Information Disclosure Statement

The Information Disclosure Statements of 11/02/01, 4/5/02 and 4/2/04 have been entered.
It is noted that pages 4 and 5 of the Information Disclosure Statement of 4/5/02 are missing from
the Image File Wrapper System. The PTO-1449 for states that there are 5 pages on the top, and
only pages 1 of 5, 2 of 5 and 3 of 5 are present. The last two pages appear to have been last in
the scanning process, and applicant is requested to resubmit those pages if possible.

The response to the requirement for information under 37 CFR 1.105 has been entered
and considered.

Drawings

The drawings filed with the application appear suitable to the examiner.

Specification

The disclosure is objected to because of the following informalities: The Brief
Description of the Drawings does not refer to each figure individually as required. Figure 2 is
not specifically described in this section.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or
> any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and
> requirements of this title.

Claims 1-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed
to non-statutory subject matter. The claims are drawn to methods of manipulating data. The
steps of the method merely rearrange stored data, to produce a "code" which must be further
interpreted by the user to be useful. This coded result is not concrete, tangible and useful as

required. Further, The resulting data is only stored, and not output or displayed to the user.
Further, the steps of the method do not actually represent anything about the particular biological
sample identified in the preamble. No steps in the method measure any given sample, or assess
the sample for anything related to the stored codes. As such, these claims are not statutory. See
MPEP 2106: "For such subject matter to be statutory, the claimed process must be limited to a
practical application of the abstract idea or mathematical algorithm in the technological arts. See
Alappat, 33 F.3d at 1543, 31USPQ2d at 1556-57 (quoting Diamond v. Diehr, 450 U.S. at 192,
209 USPQ at 10). See also Alappat 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J.,
concurring) ("unpatentability of the principle does not defeat patentability of its practical
applications") (citing O 'Reilly v. Morse, 56 U.S. (15 How.) at 114-19). A claim is limited to a
practical application when the method, as claimed, produces a concrete, tangible and useful
result; i.e., the method recites a step or act of producing something that is concrete, tangible and
useful. See AT &T, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is
statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in
State Street, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being
claimed (as in Alappat, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc)."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the
subject matter which the applicant regards as his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for
failing to particularly point out and distinctly claim the subject matter which applicant regards as
the invention.

In claim 1, the goal of the preamble is to encode a characteristic of a sample, however,
the steps of the method do not lead to that goal. No sample is obtained, or assessed for any
characteristic and there is nothing to encode. Further, the steps of the method only rearrange
data in a database, without relating any of the information to the sample. As such, the metes and
bounds of the claim are indefinite.

Claims 2-5 do not remedy these problems, and merely further limit the codes, or the storage of information. Claim 6 recites an intended use of the code "for assignment to a sample" however this intended use does not actually assign the code, but merely provides all the stored codes. Claim 7 provides a sample, but does not indicate how the steps of claim 1 or claim 6 are to be applied to it. Claims 8-10 further limit the step of providing codes, but do not actually assign a code to a sample or encode a characteristic of the sample.

The metes and bounds of claim 11 are unclear, as it would appear the sample has already been coded- If the sample already has a pre-coordinated code assigned, what is the method of claim 1 to do?

Claims 12-13 do not remedy this problem, but merely limit how the query is to be received. Claims 14-17 do not lead to the encoding of a characteristic of a sample, but merely further limit the coding combination process to lead to pre-coordinated code.

Claims 18-30 have the same problems as claims 1-17 listed above. For example, the computer program does not have any steps that lead to the encoding of a characteristic of a biological sample. The steps of the program merely rearrange data.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1.   Determining the scope and contents of the prior art.
2.   Ascertaining the differences between the prior art and the claims at issue.
3.   Resolving the level of ordinary skill in the pertinent art.
4.   Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Keizer (2001) in view of Berman (1996).

The claims are drawn to methods of pre-coordinating sets of codes in a coding system, and storing the coordinated codes in a database, for further use in classification of samples or database records. The coordinated codes can have associated lexical or semantic codes, can utilize SNOMED codes, utilize basic syntax, be displayed from a menu system etc. The method can be carried out on a computer, with queries and data relay through the internet or internal network. The codes can correspond to diagnosis, tissue, or procedural aspects of medicine. Computer program products for performing the methods are also claimed.

De Keizer et al. (de Keizer, N. F. Yearbook of Medical Informatics 2001, pages 263-270 : PTO-1449) disclose the application and combination of coding systems for use in coding medical data. The medical data can include diagnostic and procedural codes. De Keizer discusses a number of coding systems, including SNOMED, and discusses how to reduce or combine them to an ideal terminological system. The SNOMED system is discussed at pages 267-268. The various types of codes, syntax, and database structure is discussed. At page 267, the concatenation of SNOMED codes for a particular data record is discussed. [(Lung+granuloma+M.tuberculosis+fever) also represents tuberculosis] These concatenated combinations can be created and defined prior to coding data records. This portion of the reference also discusses SNOMED RT, a program which utilized concatenated SNOMED codes for diagnosis, or encoding the characteristics of a data record. De Keizer also discusses UMLS, GALEN, ICD and NHS coding systems. Each of these systems have their own codes, syntax, and database structure. De Keizer discusses how each can be reduced to an ideal terminological system.

De Keizer does not specifically provide methods of creating pre-coordinated codes, or computer programs therefor, nor does de Keizer specifically speak to using the methods over a computer network such as the internet.

Berman (Berman, J.J. et al. Modern Pathology (1996) vol 9. no.9. pages 944-950) disclose methods of creating SNOMED-based databases for automated coding of pathology samples or pathology data records. Berman et al. note that the creation of computer programs for automated extraction and coding of pathology records is trivial. "Automatic (computer-

driven) coding provides uniformity and completeness of SNOMED databases and offers the possibility of customized recoding for an entire collection of reports using any nomenclature and any set of coding algorithms." (Abstract). A database described by Berman comprises data records which comprise both SNOMED codes and semantic or lexical information. The users can choose the coding system to be used by the automatic encoder, and may specify definitions. The algorithms used to construct the databases can be tailored to the intended use of the database, for example, for case histories, or for diagnosis. The systems can be implemented over the Internet. Berman also discloses the use of the database for identifying and requesting potentially useful or extra tissue sections from a tissue bank.

Taken together, the instant invention appears to be the same or slightly different from the prior art of creating coding systems for medical data wherein codes are combined or concatenated for more specific definitions of a sample or medical record as set forth by de Keizer.

One of ordinary skill in the art at the time the invention was made would have been motivated to select and evaluate the automated coding system of Berman with the known SNOMED concatenation of codes, as automated encoding provides uniformity and completeness of databases, and offers customization of the interfaces. Further, the automation of known methods in and of itself, cannot impart non-obviousness of the method. (In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194.(CCPA 1958). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

MARY K. ZEMAN
PRIMARY EXAMINER